

## Disease Team Therapy Planning I

### RFA 10-05: CIRM Disease Team Therapy Development Awards

The Disease Team Therapy Development Award initiative is an expansion of our original Disease Team Award Initiative. The purpose of CIRM Disease Team Therapy Development Awards is to enable preclinical and/or early clinical development of novel therapies derived from targeting stem cells or utilizing direct reprogramming that may offer unique benefit with well-considered risk to persons with disease or serious injury. The Disease Team Therapy Development Awards RFA has two parts: 1) a Part I Planning Award will support up to six months of team assembly, planning and proposal development for the Research Award application (which is the subject of this Part I competition), and 2) a Part II Research Award will support actively managed teams to conduct milestone-driven translational research (which will be the subject of a supplement to this RFA anticipated to be released in summer, 2011).

The key objectives of the Part II Research Award will be to achieve, within 4 years of the Part II Research Award start date, one or more of the following: 1) file a complete and well-supported IND with the Food and Drug Administration (FDA) (and, if desired, other regulatory agencies) and/or 2) complete a Phase I and/or Phase I/II clinical study that will evaluate preliminary safety and preliminary biological activity/early efficacy in humans and/or 3) complete a Phase II clinical study that will evaluate efficacy and could lead to more definitive efficacy studies.

Please see the RFA for full details.

RFA 10-05: CIRM Disease Team Therapy Development Awards [pdf] (amended on 02/01/11)

### Application Process

Submission of an application for the Part I Planning Awards involves a two-step process. Any eligible applicant may submit a Letter of Intent (LOI, see section V for eligibility criteria). Applications will only be accepted from Principal Investigators (PIs) who submitted an LOI that was accepted by CIRM. The PI and the proposed development candidate must be the same as those described in the LOI; otherwise, the application is deemed ineligible.

### Letter of Intent (LOI) Instructions

A PI may submit only a single Letter of Intent for this RFA. **The LOI and accompanying signature page must be submitted online using the CIRM Grants Management Portal, and must be received by CIRM no later than 5:00PM (PST) on January 26th, 2011. No exceptions to this deadline will be made.** To submit a Letter of Intent:

1. Go to the Grants Management Portal (<https://grants.cirm.ca.gov>) and **log in with your existing CIRM Username and Password**. If you do not have a Username, Click on the **"New User"** link and follow the instructions to obtain a CIRM Username and password. **Please note: the letter of Intent must be submitted through the profile of the PI's as opposed to a secondary user.**
2. After logging in, your home page will display a list of open RFAs. Click on the **"Apply for this grant"** link corresponding to the **CIRM Disease Team Therapy Development Awards**.
3. Complete each section by clicking on the appropriate link and following the posted instructions. The signature page template can be found in the **"Upload Required Documents"** section. You should print the template, sign and then scan the original signature page to a PDF document. Clicking the **"Upload"** link will allow you to upload your completed signature page. The completed Letter of Intent must be submitted online.
4. The **"Done with Letter of Intent"** button becomes enabled when all required fields have been completed and documents have been uploaded. Your LOI will be submitted once the **"Done with Letter of Intent"** button is selected. **After it has been submitted, you will no longer be able to make changes to your Letter of Intent.**
5. To ensure the process is complete, go back to your home page and check the list under **"Your Preliminary Applications"**. The status for Disease Team Therapy Development Awards should read **"submitted"**.

**The LOI and accompanying signature page must be submitted online using the CIRM Grants Management Portal, and must be received by CIRM no later than 5:00PM (PST) on January 26th, 2011. No exceptions to this deadline will be made.**

## Application Instructions and Forms

Only those applicants that submitted an LOI that was accepted by CIRM may submit an application.

The application for the CIRM Disease Team Therapy Development Part I Planning Awards consists of **four parts**:

**Part A: Application Information Form** (Web-based form) **Part B: Disease Team Therapy Development Part I Planning Award Proposal** (MS Word template) **Part C: Biographical Sketches for Principal Investigator and Planning Leader** (MS Word template) **Part D: Related Business Entities Disclosure Form** (Adobe PDF template)

Application forms and templates are available within the CIRM Grants Management Portal. To access the application materials:

1. Go to the Grants Management Portal (<https://grants.cirm.ca.gov>) and **log in with your existing CIRM Username and Password**. 2. After logging in, your home page will display a list of open RFAs. Click on the "**Apply for this grant**" link corresponding to the **CIRM Disease Team Therapy Development Awards**. 3. Complete each section of the Part A form by clicking on the appropriate link and following the posted instructions. Templates for Parts B-D can be found in the "**Upload Required Documents**" section.

**All four parts of the Part I Planning Award application must be submitted together and received by CIRM no later than 5:00PM PDT on March 22, 2011, in both electronic form (via the Grants Management Portal) and in hard copy (a signed original and five copies). It is the applicant's responsibility to meet this deadline; no exceptions will be made.** The electronic copy of all four parts of the Part I Planning Award application must be submitted online as instructed on the CIRM Grants Management Portal (<https://grants.cirm.ca.gov>). The original hard copy of the application (consisting of Parts A-D) must be signed by both the PI and the applicant institution's Authorized Organizational Official (AOO). The original application plus 5 hard copies (preferably double-sided) should be sent via express mail or courier service to:

Disease Team Therapy Development Part I Applications  
California Institute for Regenerative Medicine  
210 King Street  
San Francisco, CA 94107

## Schedule of Deadlines and Reviews

Part I Planning Award	
Letters of Intent	Due 5:00 pm (PST), on January 26, 2011
Part I Planning Applications	Due 5:00 pm (PDT), on March 22, 2011
Anticipated Review of Planning Applications by Grants Working Group (GW/G)	Late May 2011
Anticipated Review and Approval by ICOC	August 2011
Funding of Planning Awards	September 2011
Planning Period	September 2011 - February 2012

Part II Research Award	
Part II Research Applications	Due January 2012

Anticipated Review of Research Award Applications by GWG	Spring 2012
Anticipated Review and Approval by ICOC	Summer 2012
Earliest Funding of Research awards	Summer 2012

**No exceptions will be made to the indicated deadlines.**

**ICOC approval:**

Jun 27, 2008

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**Source URL:** <http://www.cirm.ca.gov/our-funding/research-rfas/disease-team-therapy-planning-i>